

Application Serial No.: 10/748,484
Amendment dated: February 21, 2006
Response to the November 18, 2005 Office Action

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REMARKS

Upon entry of the foregoing amendments, claims 1 – 2 are currently pending in the present Application. Applicants have amended claim 1 to now recite an “isolated antibody.” Applicants have also amended claim 1 to remove reference to non-elected sequences. Basis for these amendments can be found in the Specification as originally filed. Applicants assert that the present amendment adds no new matter.

THE §101/§112, FIRST PARAGRAPH REJECTIONS

The Examiner has rejected claim 1 under 35 U.S.C. §101, alleging that the claimed invention is directed to non-statutory subject matter.

Applicants have amended claim 1 to now recite an “isolated antibody.” Basis for this amendment can be found in the Specification as originally filed. In light of the present amendment, Applicants believe that the present rejection is now moot.

The Examiner has rejected claims 1 and 2 under 35 U.S.C. §101 and §112, first paragraph, alleging that the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility, and thus, one skilled in the art would not know how to it. Specifically, the Examiner has stated that Applicants “asserted utility” for Zcyto10 “to promote wound healing” is not specific or substantial because the Specification does not disclose the role of Zcyto10 in wound healing or the result of applying a therapeutic of the present invention to a wound or a burn to promote wound healing.

Applicants strongly disagree. Applicants respectfully remind the Examiner that they “need only provide one credible assertion of specific and substantial utility.” See e.g. M.P.E.P. §2107(II). Applicants strongly assert that they have in fact provided a credible, specific and substantial utility: **Zcyto10 is useful in promoting wound healing.** As stated in the M.P.E.P. §2107.01(I)(A) a “specific utility” is one where an Applicant “discloses a specific biological activity” and “reasonably correlates that activity to a disease condition”. As stated above, Applicants have indeed disclosed a “specific and substantial” biological activity for Zcyto10: to promote wound healing.

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Moreover, in Example 4, Applicants specifically disclose that Zcyto10 expression is up-regulated in wounded skin. Accordingly, Applicants assert that they have in fact disclosed a "specific utility": Applicants disclosed that Zcyto10 is upregulated in wounded skin" (*i.e.* a "specific biological activity") and thus would be useful in the treatment of burns or to promote wound healing (*i.e.* "reasonably correlates that activity to a disease condition").

The Examiner has also stated that the asserted utility is not presented in a "ready-to-use, real-world application" and, as such, "is not substantial."

Again, Applicants disagree. Applicants have also described to one skilled in the art how to use Zcyto10 for the treatment of such a burn or a wound. *See e.g.* Specification at pg. 34, lines 11-27. Applicants assert that one skilled in the art would easily recognize that the Zcyto10 would be useful to promote wound healing and how to use the same to promote such wound healing.

Furthermore, Applicants assert that the M.P.E.P. §2107.01(I)(B) specifically states that Office personnel must be careful not to interpret the phrase "immediate benefit to the public" or other similar phrases to mean that products based on the claimed invention must be "currently available" in order to satisfy the utility requirement, but rather "*any reasonable use that an Applicant has identified that can be viewed as providing a public benefit should be accepted as sufficient.*" Further, the Courts have repeatedly found that the *mere identification* of a pharmacological activity that is relevant to the asserted use provides such "an immediate benefit to the public" and thus satisfies the utility requirement. *See e.g.* M.P.E.P. §2107.01(III)(A); *see also Nelson v. Bowler*, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980), which states:

Knowledge of the pharmacological activity of any compound is obviously beneficial to the public. It is inherently faster and easier to combat illnesses and alleviate symptoms when the medical profession is armed with an arsenal of chemicals having known pharmacological activities. Since it is crucial to provide researchers with an incentive to disclose pharmacological activities in as many compounds as possible, **we conclude that adequate proof of any such activity constitutes a showing of practical utility.**

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In addition, the Courts have also found utility for therapeutic inventions that were at very early stages in development, based solely on the claimed biological activity of the compound:

We perceive no insurmountable difficulty, under appropriate circumstances, in finding that the first link in the screening chain, *in vitro* testing, may establish a practical utility for the compound in question. Successful *in vitro* testing will marshal resources and direct the expenditure of effort to further *in vivo* testing of the most potent compounds, thereby providing an immediate benefit to the public, analogous to the benefit provided by the showing of an *in vivo* utility.

See e.g. *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995). Accordingly, an Applicant is not required to demonstrate that a claimed invention is a fully effective drug for humans. See e.g. M.P.E.P. §2107.01(III).

Applicants assert that Zcyto10 has a specific and substantial asserted utility that would be easily recognizable, and understood and appreciated by one skilled in the art upon reading the present Application. The utilities of the claimed invention described above provide immediate benefit to the public. That is all that is required under 35 U.S.C. §101. Accordingly, Applicants respectfully request consideration and withdrawal of the present rejections under 35 U.S.C. §101 and §112.

The Examiner has also rejected claims 1 – 2 under 35 U.S.C. §112, second paragraph, as indefinite for citing non-elected sequences.

Applicants have amended claim 1 to remove reference to non-elected sequences. Accordingly, Applicants believe that this rejection is now moot.

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On the basis of the above amendments and remarks, Applicants believe that each rejection has been addressed and overcome. Reconsideration of the application and its allowance are requested. If for any reason the Examiner feels that a telephone conference would expedite prosecution of the application, the Examiner is invited to telephone the undersigned at (206) 442-6558.

Respectfully Submitted,

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Enclosures:
Amendment Fee Transmittal (in duplicate)